



DEPARTMENT OF VETERANS AFFAIRS

8320-10

38 CFR Part 3

RIN 2900-AO09

Extension of Statutory Period For Compensation For Certain Disabilities Due To
Undiagnosed Illnesses and Medically Unexplained Chronic Multi-Symptom
Illnesses

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) is issuing this interim final rule to amend its adjudication regulation regarding compensation for disabilities suffered by veterans who served in the Southwest Asia Theater of Operations during the Persian Gulf War. This amendment is necessary to extend the period during which disabilities associated with undiagnosed illnesses and medically unexplained chronic multi-symptom illnesses must become manifest in order for a veteran to be eligible for compensation.

DATES: Effective Date: This interim final rule is effective [Insert date of publication in the FEDERAL REGISTER].

Comments must be received by VA on or before [Insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted through www.Regulations.gov; by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave., NW, Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. (This is not a toll-free number). Comments should indicate that they are submitted in response to “RIN 2900-AO09 - Extension of Statutory Period For Compensation For Certain Disabilities Due To Undiagnosed Illnesses and Medically Unexplained Chronic Multi-Symptom Illnesses.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number). In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT: Nancy Copeland, Consultant, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 461-9428. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

In response to the needs and concerns of veterans who served in the Southwest Asia theater of operations during the Persian Gulf War, Congress enacted the Persian Gulf War Veterans' Benefits Act, Title I of the Veterans' Benefits Improvement Act of 1994, Public Law 103-446, which was codified at 38 U.S.C. 1117. This law provided authority for the Secretary of Veterans Affairs (Secretary) to compensate Gulf War veterans with a chronic disability resulting from an undiagnosed illness that became manifest either during service on active duty in the Southwest Asia theater of operations during the Persian Gulf War or to a degree of ten percent or more disabling during a presumptive period determined by the Secretary.

Public Law 103-446 directed the Secretary to prescribe by regulation the period of time, following service in the Southwest Asia theater of operations, determined to be appropriate for the manifestation of an illness warranting payment of compensation. It further directed that the Secretary's determination of a presumptive period be made only following a review of any credible medical or scientific evidence and the historical treatment afforded disabilities for which manifestation periods have been established, taking into account other pertinent circumstances regarding the experiences of veterans of the Persian Gulf War.

To implement 38 U.S.C. 1117, VA published a final rule to add 38 CFR 3.317, which established the framework for the Secretary to pay compensation

under the authority granted by the Persian Gulf War Veterans' Benefits Act. See 60 FR 6660, February 3, 1995. As part of that rulemaking, VA established a 2 year, post-Gulf War service presumptive period based primarily on the historical treatment of disabilities for which manifestation periods have been established and pertinent facts known regarding service in the Southwest Asia theater of operations during the Persian Gulf War. VA determined that there was little or no scientific or medical evidence, at that time, useful in determining an appropriate presumptive period for undiagnosed illnesses.

Due to the continuing lack of medical and scientific evidence about the nature and cause of the illnesses suffered by Gulf War veterans and the inadequacy of a designated presumptive period for undiagnosed illnesses, the Secretary established December 31, 2001, as the date by which an undiagnosed illness must become manifest for purposes of claims based on service in the Southwest Asia theater of operations during the Persian Gulf War. In 2001, VA further extended the period from December 31, 2001, to December 31, 2006.

In December 2001, section 202(a) of Public Law 107-103 amended 38 U.S.C. 1117 by revising the term "chronic disability" to include the following (or any combination of the following): (a) an undiagnosed illness; (b) a medically unexplained chronic multi-symptom illness (such as chronic fatigue syndrome, fibromyalgia, and irritable bowel syndrome) that is defined by a cluster of signs and symptoms; or (c) any diagnosed illness that the Secretary determines

warrants a presumption of service connection. The revised term “qualifying chronic disability,” has broadened the scope of those health outcomes the Secretary may include under the presumption of service connection. Under 38 U.S.C. 1117, a chronic disability must still occur during service in the Southwest Asia theater of operations during the Persian Gulf War, or to a degree of ten percent or more disabling during the prescribed presumptive period following such service. VA amended 38 CFR 3.317 to reflect these changes. See 68 FR 34539, June 10, 2003.

As required by Public Law 105-277, the National Academy of Sciences (NAS) conducts ongoing review, evaluation, and summarization of the scientific and medical literature for peer review regarding the possible association between service in the Southwest Asia theater of operations and long-term adverse health effects. Due to the inconclusive nature of the scientific and medical evidence concerning the manifestation period for the subject illnesses, in December 2007, VA published a final rule to further extend the manifestation period from December 31, 2006 (previously extended), to December 31, 2011. See 72 FR 68507-01. Additionally, on October 13, 2010, Congress enacted section 806 of Public Law 111-275, which directed NAS to continue to review, evaluate, and summarize scientific and medical literature associated with Persian Gulf War service and broadly expanded the time frame for NAS to complete this research, since military operations in the Southwest Asia Theater of Operations continue,

including Operation Iraqi Freedom, and no end date for the Gulf War has been established by Congress. See 38 U.S.C. 101(33).

In a report published in 2010 titled Gulf War and Health, Volume 8: Update of Health Effects of Serving in the Gulf War, NAS evaluated the available scientific and medical literature regarding the prevalence of chronic multi-symptom illnesses in Gulf War veterans. Consistent with its prior findings, NAS concluded, based on multiple studies, that there is sufficient evidence of an association between deployment to the Gulf War and chronic multi-symptom illness. NAS analyzed two follow-up studies that surveyed veterans who served in the Gulf War in 1991 in order to determine whether the increased prevalence of chronic multi-symptom illness persisted several years after such service. One study, conducted 10 years after the 1991 Gulf War, involved conducting detailed examinations and medical histories of veterans deployed to the Gulf War and non-deployed veterans of the same era. The study found that, 10 years after the 1991 Gulf War, chronic multi-symptom illness was nearly twice as prevalent in veterans deployed to the Gulf War (present in 28.9 percent of such veterans) than in the non-deployed veterans (15.8 percent). The study found that the prevalence of chronic multi-symptom illness decreased gradually over time, but remained significantly elevated 10 years after service. The other follow-up study involved a 2005 survey of veterans deployed to the 1991 Gulf War and their non-deployed counterparts of that era. That study found that 36.5 percent of the deployed veterans reported experiencing symptoms of chronic multi-symptom

illness in 2005, compared to 11.7 percent of the non-deployed veterans. While this report is limited in that it is based on self-reports, the results are statistically significant and are consistent with the other follow-up report.

The currently available scientific and medical literature thus suggests that, while the prevalence of chronic multi-symptom illness may decrease over time following deployment to the Gulf War, the prevalence remains significantly elevated among deployed veterans more than a decade after deployment. At present, there is not a sufficient basis to identify the point, if any, at which the increased risk of chronic multi-symptom illness may abate. Further follow-up studies may provide additional information relevant to this issue in the future.

Section 501(a) of Title 38, United States Code, provides that the Secretary of Veterans Affairs “[h]as authority to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department and are consistent with those laws.” Because scientific uncertainty remains as to the cause of illnesses suffered by Persian Gulf War veterans and the time period in which such veterans have an increased risk of chronic multi-symptom illness, and because scientific studies and NAS reviews are ongoing, in order to ensure that benefits established by Congress are fairly administered, VA is further amending 38 CFR 3.317 to extend the evaluation period from December 31, 2011, to December 31, 2016.

Administrative Procedures Act

The Secretary of Veterans Affairs finds that there is good cause under the provisions of 5 U.S.C. 553(b)(3)(B) to publish this rule without prior opportunity for public comment. Absent extension of the sunset date in the current regulation, VA's authority to provide benefits in new claims for qualifying chronic disability in Gulf War veterans will lapse on December 31, 2011. A lapse of such authority would have significant adverse impact on veterans disabled due to such disabilities. To avoid such impact, VA is issuing this rule as an interim final rule. However, VA invites public comments on this interim final rule and will fully consider and address any comments received.

Paperwork Reduction Act

This document contains no provisions constituting a new collection of information under the Paperwork Reduction Act (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This rule would not affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” which requires review by the Office of Management and Budget (OMB), as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this rule have been examined and it has been determined to be a significant regulatory action under Executive Order 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any year. This rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are: 64.109, Veterans Compensation for Service-Connected Disability.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on November 28, 2011, for publication.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Radioactive materials, Veterans, Vietnam.

Dated: December 22, 2011

Robert C. McFetridge,
Director of Regulation Policy and Management,
Office of the General Counsel,
Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 38 CFR part 3 as follows:

PART 3 – ADJUDICATION

1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

2. In § 3.317, paragraph (a)(1)(i), remove the date “December 31, 2011” and add, in its place, “December 31, 2016”.

[FR Doc. 2011-33222 Filed 12/28/2011 at 8:45 am; Publication Date: 12/29/2011]